

oral care composition remains on the oral surfaces as a thin film. Prolonged delivery of the oral care substance is made possible as the oral care substance is released from the film over time.

The oral care composition applied to the backing strip is formulated to quickly form a film on the oral surface upon direct application, the film providing sustained release of the oral care substance to oral care surfaces over time. A key advantage of the present invention is that substantivity of beneficial oral care active agents to oral tissues is enhanced, thus providing prolonged contact and activity. Conventional product forms such as dentifrice and mouthrinse, typically do not provide sufficient substantivity to maintain the actives on teeth or other oral tissues for a long enough time to be beneficial. This enhanced substantivity is provided by particular organosiloxane resins comprised of units selected from the group consisting of  $(\text{CH}_3)_3\text{SiO}_{0.5}$  "M" units,  $(\text{CH}_3)_2\text{SiO}$  "D" units,  $(\text{CH}_3)\text{SiO}_{1.5}$  "T" units,  $\text{SiO}_2$  "Q" units, and mixtures thereof.

#### Double Patenting Rejection

Claims 1-28 are provisionally rejected as being unpatentable under the judicially created doctrine of obviousness-type double patenting over Claims 1-30 of copending Application No. 10/019,031 and over Claims 1-26 of copending Application No. 10/019,038. The Examiner asserts that the present claims overlap in scope with the claims of the copending applications.

Claims 1-28 are rejected as unpatentable under the judicially created doctrine of obviousness-type double patenting over Claims 1-4 of commonly assigned US 6,406,683 in view of Suchan (US 4,032,627) and Hughes I-IV (I US 6,123,950; II US 6,024,891; III US 6,008,171; IV US 5,856,282). Claims 1 to 24 are rejected as unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 1-20 of commonly-assigned US 6,340,466 in view of Suchan and Hughes (I-IV); over claims 1-18 of commonly-assigned US 6,139,823 in view of Suchan and Hughes (I-IV); and over Claims 1-4 of commonly-assigned US 6,071,503 in view of Suchan and Hughes (I-IV). The Examiner asserts that it would have been obvious from the teachings of the citations to formulate oral care compositions with pigments and bleaching actives for teeth.

Applicants respectfully traverse the Examiner's double patenting rejection of the claims over copending Application Nos. 10/019,032 and 10/019,038.

Applicants respectfully submit that there is no overlap with the claims of copending Application No. 10/019,038. The present claims are directed to a two-component delivery system wherein the first component is a removable backing strip having sufficient flexibility so as to be readily conformable to an oral surface when the delivery system is placed thereagainst; and the second component is an oral care composition applied to the backing strip such that when the delivery system is placed on the oral surface the oral care composition contacts the oral surface. This removable backing strip is not disclosed nor claimed in copending Application No. 10/019,038.

Applicants further submit that there is no overlap with the claims of copending Application No. 10/019,031, which discloses and claims two-part compositions directed to two-part compositions wherein the first part is a composition for delivering an oral care active to an oral surface and the second part is a

protective composition applied over the first oral composition for the purpose of keeping the oral composition in place and prolonging its activity. The present backing strip, which may be a substantially water insoluble or substantially water soluble material is distinguished from the protective composition of 10/019,031, which is intended to remain with the composition comprising the oral care active. By contrast, the present backing strip is intended to be removed. The substantially water insoluble strip may be peeled away by the user and the substantially water soluble strip can be left to dissolve *in situ*.

Applicants also traverse the Examiner's obviousness-type double patenting rejection of the claims over each of Drechsler et al. (I-IV) in view of Suchan and Hughes (I-IV). However, in the interest of advancing prosecution of this case, a terminal disclaimer is filed herewith, which the Examiner indicated would overcome the obviousness double patenting rejection.

The Drechsler et al. patents each claim cosmetic compositions, which upon application to the skin or lips form a transfer resistant film. The compositions comprise (a) an organosiloxane resin optionally in combination with a dimethicone gum or a fluid diorganopolysiloxane polymer as film forming agent, (b) a volatile carrier and (c) pigment(s). The compositions contain sufficient pigments to provide the look sought by the user, i.e., to color lips or other areas of facial skin such as the eyelids. Importantly, the compositions provide a durable film that resists degradation over time.

There is no disclosure in any of the Drechsler patents that such film forming compositions comprising an organosiloxane resin would be applicable for delivering actives to teeth surfaces, which are different from skin and are in a different environment. The substantivity and retentivity of the organosiloxane film on teeth could not have been predicted from the performance of such films when applied to skin as disclosed in the Drechsler patents.

The Hughes (I-IV) patents relate to oral care compositions, which are improved in terms of the surface substantivity or residuality of lipophilic agents on the surface of e.g., teeth, dentures, and oral cavity. The lipophilic agent is selected from the group consisting of flavor, perfume, coolant, antimicrobial agent, and mixtures thereof. The compositions comprise a dimethicone copolyol or an aminoalkyl silicone having an aminoalkyl siloxane content of from 0.1% to 2% on a repeating unit basis. When in the form of denture cleansers, the compositions contain a bleaching agent in addition to the silicone component and lipophile.

Suchan discloses a non-toxic tooth whitening composition consisting essentially of the following component solutions:

- (a) a first component comprising zinc oxide, approximately 6.3 percent; ammonium hydroxide, approximately 17.1 percent; ammonium carbonate, approximately 11.3 percent; with the balance water;
- (b) a second component comprising said first component as approximately 9.85 percent; a 70% solution of a mucilaginous bodying material, capable of functioning as a film forming agent, in isopropyl alcohol approximately 39.4 percent; methyl cellulose approximately 1.5 percent; with the balance ethanol; said second component comprising 70 percent of the total composition;

- (c) a third component comprising; said second component as approximately 70 percent; a non-toxic yellow food dye solution, approximately 15 percent; titanium dioxide, approximately 4 percent; with the balance ethanol.

Disclosed as mucilaginous bodying and film forming material are hydroxypropyl methylcellulose, Carboset Resin 514-A which is an acrylic resin, and conventional natural bodying agents, for example, gum tragacanth.

There is no disclosure whatsoever in Hughes (I-IV) or Suchan with regard to the present organosiloxane resins alone or in combination with a fluid diorganopolysiloxane polymer as film forming agent, much less that such organosiloxane resin film would have sufficient substantivity to maintain actives on teeth or other oral tissues for a sufficient length of time to be beneficial, and even less that such oral care composition could be delivered by use of a removable backing strip.

Applicants submit that no motivation is provided for combining the teachings of Hughes et al. or Suchan dealing with compositions for the oral cavity and the teachings of Drechsler dealing with compositions for application to skin (specifically lips and eye area). Even if there were motivation to combine such teachings, Applicants submit it would not have led to the present compositions.

#### Terminal Disclaimer

In the interest of advancing prosecution of this case, submitted herewith is a Terminal Disclaimer in response to the Examiner's double patenting rejection of the claims over commonly assigned US 6,406,683; US 6,340,466; US 6,139,823 and US 6,071,503 and authorization to charge the required fee to Deposit Account No. 16-2480.

#### CONCLUSION

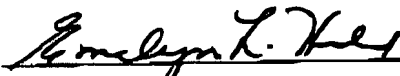
Applicants respectfully request reconsideration of this application, entry of the amendments, withdrawal of the double patenting rejection, acceptance of the terminal disclaimer and allowance of all application claims.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Markings to Show Changes Made".

Respectfully submitted,

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**Version With Markings to Show Changes Made**

**In the Claims**

Claims 20, 23, 25 and 27 are amended as follows.

20. (Amended) The delivery system of either of Claim 1 or Claim 9 wherein the backing strip is substantially water insoluble.

23. (Amended) The delivery system of either of Claim 1 or Claim 9 wherein the backing strip is substantially water soluble.

25. (Amended) A method for delivering an oral care substance to at least one surface of the oral cavity, comprising the steps of: (1) applying the backing strip of the delivery system with the oral care composition of either of Claim 1 or Claim 9 coated thereon to the surface(s) of the oral cavity; (2) removing the backing strip from the surface(s) of the oral cavity, wherein the oral care composition remains on the surface(s) of the oral cavity after the backing strip is removed.

27. (Amended) A method for delivering an oral care substance to at least one surface of the oral cavity, comprising the steps of: (1) applying the backing strip of the delivery system with the oral care composition of either of Claim 1 or Claim 9 coated thereon to the surface(s) of the oral cavity; (2) allowing the backing strip to dissolve in situ, wherein the oral care composition remains on the surface(s) of the oral cavity after the backing strip has dissolved.